

**OTHER TRANSACTION AGREEMENT (OTA)**

**OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)**

**BETWEEN**

**Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591-6717**

**AND**

**THE UNITED STATES OF AMERICA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE  
200 C Street, S.W.  
WASHINGTON, DC 20515**

**CONCERNING**

**Novel Antibodies against Influenza Virus, Emerging, re-Emerging, and pre-Emerging pathogens**

**Modification No. 0008**

**Effective Date: June 15, 2020**

PR No.: OS 206444 \$18,693,213; OS 233799 \$19,274,081; OS234612 \$278,812; OS 253326 \$5,751,859;  
OS 256115 \$92,984,806; OS258142 \$9,247,916; OS260197 \$85,094,597

Total Amount of the Agreement: \$289,156,605 (Changed)

Total Estimated Government Funding of the Agreement: \$231,325,284 (Changed)

Total Estimated Recipient Funding of the Agreement: \$57,831,321 (Changed)

Funds Obligated: \$231,325,284 (Changed)

Period of Performance: September 25, 2017 through May 31, 2026 (Unchanged)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027

(b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 199TWLN

(b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994047

(b) (4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994044

(b) (4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027  
(b) (4) (CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 199TWLN  
(b) (4) (CLIN 0003)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 199TWRY  
(b) (4) CLIN 0001 and (b) (4) CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 1992019  
(b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class: 25106; Appropriation Yr: 2020, CAN: 1992020  
(b) (4) CLIN 0001 and (b) (4) CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25103; Appropriation Yr: 2020, CAN: 199COV2  
(b) (4) CLIN 0003; (b) (4) CLIN 0004 and (b) (4) CLIN 0005 and  
(b) (4) CLIN 0006)

Line of Accounting and Appropriation: Object Class: 25103; Appropriation Yr: 2020, CAN: 199COV2  
(b) (4) (CLIN 0004)

Line of Accounting and Appropriation: Object Class: 25103; Appropriation Yr: 2020, (b) (4)  
(b) (4) CAN: 199COV2 CLIN 0004; (b) (4) : 199C002 CLIN 0005)

**PURPOSE:** The purpose of this modification is to (1) increase funds to CLIN 0004 (IND enabling studies for (b) (4) and increase funds to CLIN 0005 representing a first in human study (FIH). Specifically the hospitalized clinical study totals (b) (4) and the ambulatory clinical study totals (b) (4) (2) Clarify the protocol amendment process in Article IV, (3) Clarify the logistics in Article VII regarding reimbursement of payment, and (4) add COVID-19 guidance

Beginning with the effective date of this modification, the Government and Other Transaction Agreement holder mutually agree as follows:

1. Agreement No.:  
HHSO100201700020C Line Items and  
corresponding values:

Funding for this OTA is revised as  
follows:

Line Item	Recipient Cost-Share	Government Cost-Share	Total Estimated Cost	Total Government Funds Obligated to Date
0001 - Base Period	(b) (4)			\$12,118,721
0001-MERS				\$164,378
0001-FILO				\$278,812
0002 - Option 1				\$22,947,315
0003 - Option 2				\$16,977,483

0004 - Option 3	(b) (4)	\$69,925,287
0005 - Option 4		\$ 92,544,903
0006 - Option 5		\$14,233,381
0006 - Option 5		\$2,135,007
*-Contingency fee	(b) (4)	<b>Total:</b> \$231,325,287

**Note:**

- (i) Internal Expenses. Internal expenses will be determined based on actual labor hours for the activities performed, multiplied by a single, fully-burdened FTE rate not subject to true-up, calculated for the Research & Development organization which will be working on the programs under this Agreement. This rate will be adjusted annually based on the CPI adjustment methodology outlined in the final cost proposal. The Contracting Officer will request documents supporting adjustments in the CPI.
- (ii) External (Subrecipient or Affiliates) Expenses. External expenses will be billed based on actual third-party charges submitted to Regeneron.
- (iii) Drug Supply. Drug supply manufactured at a Regeneron facility will be billed based on a fully-allocated cost methodology which includes direct variable, direct fixed and indirect cost allocations (See the 9/14/17 proposal). Drug manufactured by a third party contract manufacturer will be billed based on actual third party charges submitted to Regeneron.
- (iv) G&A. G&A expenses will be billed for external expenses and drug supply based on a set rate not subject to true-up. A negotiated rate agreement or rate documentation shall be provided in the sub recipient agreement.

2. Under **ARTICLE IV, MANAGEMENT OF THE PROJECT**, paragraph **C (Document Review)** is deleted and revised as follows:

**C. Document Review**

The Recipient shall provide the Government sufficient opportunity to review study protocols, reports, and regulatory correspondence as set forth in Attachment 2. The Government's review and comments on these documents are non-binding and advisory in nature. Specific timelines for document review and responses are outlined in Attachment 2, Reporting Requirements.

If the Government objects to a protocol amendment and Regeneron proceeds despite such objections, the Government would not be obligated to fund additional activities associated with the amendment.

3. Under **ARTICLE VII OBLIGATION OF FUNDING & FINANCIAL TERMS**, paragraph **B (Payments)** is deleted and revised as follows:

**B. Payments**

The Recipient has and agrees to maintain an established accounting system that complies with GAAP standards and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Government funds. Recipient will not be required to maintain Government funds in a separate, interest-bearing account. Further, Recipient may request and receive payment for invoices received from an Affiliate or Sub-Recipients before Recipient actually makes payment on such invoices. Government auditors may confirm adequacy of accounting system. Recipient's properly prepared invoice(s) will be submitted for payment quarterly in Adobe Acrobat (.pdf) format, along with the submission of hard copy to the OTAS; provided that the first three invoices shall be submitted for payment on a bi-monthly (every other month) basis for the bi-monthly periods ending on November 30, 2017, January 31, 2018 and March 31, 2018. If directed by the OTA0, the invoice shall be accompanied by appropriate documentation to support the payment request to support a



reasonableness determination. However, Recipient will be required to prepare and maintain records, with supporting documentation that is consistent with commercial practices. Each invoice must contain the following information in order to be deemed properly prepared:

1. Name and address of Recipient
2. Invoice Date and Invoice Number
3. Agreement Number
4. Description, quantity, unit of measure, unit price, and extended price (if applicable)
5. Recipient cost share
6. Name and address of OTAR official to whom voucher is to be sent
7. Name, title, phone number, and mailing address of person to notify in the event of a defective invoice
8. Taxpayer Identification Number (TIN)
9. Electronic funds transfer (EFT) banking information
10. The Recipient will convert foreign currency costs to US dollars based on the daily rates interfaced to the Oracle system from the Reval Treasury system on the invoice transaction date.
11. Invoices must include cumulative total costs submitted for reimbursement to date, adjusted (as applicable) to show any amounts suspended by the Government

Payments will be made for costs incurred and do not constitute financing payments. Payment will be made for the performance of services under this assistance agreement, whether or not the services achieve the intended result of the deliverable, except in the case a result or deliverable is not achieved as a result of Regeneron's gross negligence or willful misconduct. Deliverables under Attachment 2 of this Agreement must still be delivered, regardless of failure to achieve initially intended result with performance of any additional required work to be compensated on the same basis for services performed.

Documents should be delivered electronically to the OTAO, OTAS, OTTR, PSC, and e-room electronically. Unless otherwise specified by the OTAO, all deliverables and reports furnished to the Government under this Agreement (including invoices) shall be addressed as follows:

NAME	Email invoices to	Address**
Carl A. Newman (OTAO)	<a href="mailto:Carl.newman@hhs.gov">Carl.newman@hhs.gov</a>	ASPR-CMA BARDA O'Neill House Office Bldg 200 C Street, SW, 21C06 Washington, D.C. 20515
Karl Erlandson (OTTR)	<a href="mailto:Karl.erlandson@hhs.gov">Karl.erlandson@hhs.gov</a>	ASPR BARDA O'Neill House Office Bldg 200 C Street, SW, 21C06 Washington, D.C. 20515
PSC	<a href="mailto:Psc_Invoices@psc.hhs.gov">Psc_Invoices@psc.hhs.gov</a>	
E-Room:	(As provided by the Government)	

\*\*If packages are shipped, please contact the Contracting Officer for specific instructions during the COVID-19 quarantine period.

Note: The address in the table is correct for parcels shipped via U.S. Postal Service, United Parcel Service (UPS), and Federal Express (FedEx). If shipping is through another private carrier please contact a Government representative for special instruction.

The Recipient agrees to promptly notify the OTAO in writing if there is an anticipated overrun or unexpended balance (greater than 10 percent) of the estimated costs for the Base Period or any ~~Option and the reasons for the variance.~~

If Regeneron exceeds enrollment over the approved sample for any future clinical trials, Regeneron will assume 100% of the cost of enrolling those patients. Even upon approval of the study design by the Joint Oversight Committee (JOC) and the contracting officer, retrospective payments will not be considered.

In addition, Regeneron must adhere to the recommendation of the iDMC. If not, Government support for the study will end unless there is an agreement made by the JOC and the contracting officer to proceed against the iDMC recommendation.

~~The Government will pay in US dollars all proper invoices within 30 days of receipt or pay~~  
interest on any amounts due in accordance with the Prompt Payment Act.

4. HHS reserves the right to exercise priorities and allocation authority with respect to this contract, to include rating this order in accordance with 45 CFR, Part 101, Subpart A-Health Resources Priorities ~~and Allocation System.~~

All other terms and conditions remain the same.

FOR THE UNITED STATES OF AMERICA  
OFFICE OF ACQUISITION MANAGEMENT,  
CONTRACTS & GRANTS SECRETARY  
~~FOR PREPAREDNESS AND RESPONSE~~

(b) (6)

6/15/20

(Signature)

Carl A. Newman

Other Transaction Agreement Officer, BARDA

(Date)

FOR Regeneron Pharmaceuticals, Inc.

(b) (6)

Jun 13, 2020

(Signature)

Robert E. Landry,

Executive Vice President, Finance and Chief Financial Officer, Regeneron Pharmaceuticals, Inc.

(Date)

END OF MODIFICATION No. 0008 TO HHSO100201700020C